Lawrence Berkeley National Laboratory Contract Assurance Council Monthly Meeting Minutes

Wednesday, November 8, 2006 University of California—Office of the President Franklin Building, Room 9024

CAC members or representatives present:

Bob Van Ness Susan Thomas for Jeff Gary Falle for Bruce
John Birely Blair Darling (by phone)

Buck Koonce Judy Boyette Patrick Reed

Bill Eklund John Layton, by phone

CAC members absent:

Bob Foley Larry Coleman Al Diaz

Anne Broome John Oakley

UCOP Staff:

Jim Hirahara Sharon Eklund

Guest participants:

Sandy Merola, LBNL
Howard Hatayama,
LBNL
John Chernowski, LBNL
Ron Nelson, UCOP

Introductory Remarks/Action Item Review

Bob Van Ness welcomed members and guests to the Contract Assurance Council (CAC) monthly meeting. He acknowledged the LBNL 75th Anniversary celebration dinner on November 14 where the Secretary of Energy would be the keynote speaker and the Laboratory's hosting of the Secretary's meeting with DOE and NNSA Laboratory Directors on the following day. Van Ness also congratulated LBNL on various recent recognitions, particularly the award of a Nobel Prize in Physics to George Smoot.

Corrective Action Management Program

John Chernowski, LBNL Office of Contract Assurance (OCA) Manager, explained that there are four major elements of the program:

• Corrective Action Tracking System (CATS)—LBNL requires all divisions to use the system, and it is clear who has responsibility for entering data. The Laboratory continues to encourage a culture that rewards disclosure. Few of the open findings in CATS currently are a result of DOE surveillance activities. The findings self-disclosure rate is over 95%, and there have been approximately 2500 entries in the last year. There was discussion that it is important for the Laboratory to consider

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- when each new issue arises, whether the Laboratory already knew of the issue and whether it should have already been entered into CATS.
- Trending and Analysis—The current OCA analysis is focusing on "high" and "medium" findings, and they are currently trending significant events (such as injuries and Price-Anderson Amendments Act findings). They have closed 90% of the entries.
- Extent of Condition Review—"Extent of condition" describes how widespread the issue is (local to institutional). The focus here is on the most significant and most likely to recur issues. OCA is planning to develop protocols and thresholds for extent of condition review.
- Effectiveness Review—OCA is planning to develop protocols and thresholds in this area as well.

The new OCA hire will focus on EH&S issues. Chernowski distributed a sample CATS report, focusing on oldest "past due" items. As a trial period until the 851 OSHA rule becomes effective in February 2007, LBNL is evaluating new entries in CATS to see if they meet the thresholds for reporting under the rule. It appears that five or six entries might meet the threshold. The current CATS protocol allows the issue owner to change the end date, but Institutional Assurance or the appropriate manager must first approve the change. The Council suggested that OCA study the history of changes to Target Due Date for trends. Bill Eklund recommended that OCA request a Laboratory Counsel briefing on how to prepare for the 2006 Discovery Amendments to the Federal Rules of Civil Procedure. The Council commended LBNL for their accomplishments in this area so far and expressed their interest in hearing about progress in a future briefing (in six to ten months).

Select Agents/Controlled Substances

Howard Hatayama, LBNL EHS Division Director, reported on the use of select agents at LBNL. The three Principal Investigators (PIs) who are authorized by the Department of Justice to handle select agents perform this work in a Bio-safety Level-2 laboratory. LBNL has designated a Bio-safety officer and an Alternate. The bio-safety lab itself is small, with card key access, video camera surveillance, and visitor escorting. The PIs handle only one strain of select agent at a time, and disinfect the area immediately after use, including autoclaving gloves and aprons. The Berkeley Fire Department has the only hard key entry access to the lab. The only employees that can order select agents are the three PIs. Upon arrival at LBNL, the agents go directly from the delivery person to the PI—the Receiving department is not involved. LBNL does not accept material from laboratories that are not registered for select agent use with the Center for Disease Control (CDC), and if they were to receive something from an unregistered laboratory, their process is to first notify the CDC. When new materials arrive, a PI performs a culture to confirm the nature of the agent. All work is contained in a bio-safety cabinet. The Council suggested that Hatayama contact his LLNL counterpart (David Leary) to compare processes.

Hatayama also described the recent LBNL "white powder" incident and response (which went largely according to documented protocol). The one area for improvement was the chain of custody of the envelope for investigatory purposes. The three LBNL select agent

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PIs are in the medical surveillance program, and their valuable expertise was sought during the incident. However, this should not substitute for maintaining formal chain of custody by authorized investigators.

Hatayama will address the controlled substances action item at a future meeting when there is more time available.

Director's Retreat

There was insufficient time remaining in the meeting for Sandy Merola, LBNL Deputy Chief operating Officer, to give a briefing on the Director's Retreat. He did, however, provide a brief description of the suicide of an LBNL staff member (also a UCB professor) in a jump from Building 50. The Laboratory is providing communication, counseling, family support, and dealing with death support in the aftermath of the incident, and they are proud of the positive response that the staff has demonstrated in caring for each other. DOE has had three on-site suicides in last the 18 months and has assembled a task force to study what might be done in terms of prevention. The DOE was complimentary of the professionalism of the Laboratory response to the incident. They reviewed the LBNL Employee Assistance Plan, found it actively utilized, and encouraged more awareness education of the staff on the services available.

Wrap Up

The Council members unanimously approved the minutes of the October 11, 2006, meeting as submitted.

Action Items:

#	Responsible Party	Action	Date Added	Status
19	Merola/ Burnside LBNL	 Define operational requirements and associated agreements in regard to LBNL research on UCB campus. This includes ES&H and other operational requirements. Share results of the upcoming meeting of the Burnside Committee. 	06/14/06 (modified 10/13/06)	OPEN
21	McGraw/ Hatayama LBNL	Report on controlled substances process improvements.	06/14/06	OPEN

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24	Krupnick LBNL Nelson UCOP	 Provide further detail on LBNL Advisory Board report (independent operating ventures and need for review of oversight mechanisms references). Provide written response regarding operating ventures. Discuss UCOP plan for oversight 	08/09/06 (modified 10/13/16)	OPEN
25	McGraw LBNL	Provide Council members with the LBNL pie chart that indicates how many PIs are from various campuses and other universities.	09/13/06	OPEN
26	McGraw LBNL	Provide progress report on consolidation of authorities project and milestones for project completion.	09/13/06	OPEN
		On-going Actions		
5	Eklund UCOP	Schedule a ten-minute Executive Session at the close of each CAC quarterly meeting.	04/12/06	Quarterly Action
6	Eklund UCOP	Schedule quarterly CAC meetings to be held at LBNL.	04/12/06	Quarterly Action
7	Hirahara UCOP	Implement a call for agenda topics prior to each meeting.	04/12/06	Monthly Action
22	Fernandez LBNL Broome UCOP	 Report quarterly on supply chain initiative planned cost savings versus actual. Report on discussion regarding LBNL and UCOP purchasing alignment and economies of scale 	06/14/06	Quarterly Action
		Completed or Cancelled Actions		
1	Chernowski LBNL	Modify Risk Registry report to include a column in which BSO concurrence with the current status of the item can be indicated.	04/12/06	Cancelled
2	Chernowski LBNL	Plan C31 Risk Registry updates for the quarterly meetings and as-needed at the monthly meetings.	04/12/06	Done—next report at 07/12 meeting
3	Fernandez	Brief the Council on how LBNL is tracking	04/12/06	Done—held
	LBNL	cost savings and the current status.		on 6/14
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4	Chernowski LBNL	Schedule a dry run of the presentation to senior LBNL and BSO management of second quarter performance. (UC-internal only).	04/12/06	Done—held on 05/02
8	Merola LBNL	Provide the Council with the number of LBNL PIs working with controlled substances.	05/10/06	Done— presented on 6/14
9	Merola LBNL	Provide the Council with the quantity of controlled substances ordered by LBNL annually.	05/10/06	Done—presented on 6/14
10	Merola LBNL	Provide the Council with the number of discrete locations where controlled substances are handled at LBNL.	05/10/06	Done—presented on 6/14
11	Hatayama LBNL	Personally review LBNL controlled substance and drug precursor processes and personnel to assure appropriate controls are in place—report back to CAC.	05/10/06	Done— presented on 6/14
12	Hatayama LBNL	Personally review LBNL select agent processes and personnel to assure appropriate controls are in place—report back to CAC.	05/10/06	Done— presented on 11/08
13	Eklund UCOP	Add Select Agents as a topic to a future CAC agenda.	05/10/06	Done— presented on 11/08
14	Eklund UCOP	Add <i>Accounts payable</i> as a topic to a future CAC agenda.	05/10/06	Done— presented on 7/12
15	Krupnick LBNL	Provide CAC with further detail on the thorium inventory and reportability.	05/10/06	Done— presented on 7/12
16	Merola LBNL	Provide LBNL Advisory Board report to CAC when complete.	05/10/06	Done— presented on 8/9
17	Hirahara LBNL	Invite Aundra Richards to 07/12 Quarterly CAC Meeting.	05/10/06	Done— discussed on 6/14
18	Koonce LBNL	Identify the UCOP senior management "owner" of the LBNL bonding issue.	05/10/06	Done— presented on 6/14
20	Merola LBNL	Explain how LBNL manages Principal Investigators.	06/14/06	Done—presented on 9/13
23	Koonce/ Eklund UCOP	Provide Susan Thomas, UC-GC, a copy of the policy and procedures regarding who in Purchasing should have access to the vendor master.	07/12/06	Done—sent on 07/19

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27	McGraw	Supply the Council members with a copy	09/13/06	Done—sent
	LBNL	of the address Director Chu sent to LBNL		with
		PIs on the subject of their responsibilities.		September
				meeting
				minutes

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